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The role of microbiological criteria and risk assessment in HACCP

While HACCP systems focus on the identification and real-time monitoring of physical and chemical attributes at critical control points as a means of controlling foodborne pathogens, underlying these measurements are implicit or explicit microbiological criteria. An understanding of the development and proper use of microbiological criteria are critical to the development of effective hazard analysis critical control point (HACCP) plans, particularly in relation to conducting hazard analyses and establishing critical limits that impart the necessary degree of stringency in process controls. The development of improved techniques in quantitative microbial risk assessment would greatly enhance linking the microbiological criteria underlying HACCP to public health objectives.

Introduction

The use of hazard analysis critical control point (HACCP) as a means of systematically addressing food safety concerns is gaining acceptance internationally both by industry and regulatory agencies. While the essence of the HACCP approach is simple conceptually and readily recognized by most members of the food industry and government, implicit in HACCP are a number of sophisticated concepts that are only poorly defined and often not widely considered. One of the most unappreciated is the relationship between HACCP and microbiological criteria. The purpose of the current discussion is to explore the central role that microbiological criteria play in HACCP, identify the important role that risk assessment will play in establishing that interaction on a quantitative basis and stimulate further consideration and evolution of HACCP concepts.

Performing hazard analyses

It is widely accepted by food safety professionals that HACCP is an effective means by which food manufacturers can identify the key steps for preventing, controlling, or eliminating hazards associated with their product, thereby minimizing potential food safety problems. While this encompasses biological, chemical and physical attributes, the current discussion will focus on control of pathogenic micro-organisms. The first step in HACCP is the hazard analysis, wherein the production, manufacturing, distribution and use continuum is reviewed to evaluate the actual or potential risks associated with the product as a source of foodborne pathogens. This process typically involves three steps:

1. identification of each of the steps, pro-

cesses and ingredients associated with the product's production;
2. examination of available epidemiological data to determine if the product or any of its ingredients have been linked to specific foodborne diseases;
3. development of a microbiological profile of the product to assess the potential for the introduction of foodborne pathogens, their subsequent potential for growth and survival and the impact that the various steps in the process are likely to have on the micro-organisms. This includes assessing the capability and variability of important steps in the production/manufacturing processes to prevent, eliminate, reduce or control the presence, survival and growth of pathogenic micro-organisms.

Implicit in this process is that while one should consider all possibilities, only those that represent a clear risk (i.e. a significant hazard) should be ultimately identified as a hazard. For example, while *Vibrio parahaemolyticus* could potentially be introduced and grow in raw poultry meat, the low probability that this marine micro-organism would cause a problem in this product would not support its inclusion as a potential hazard. Also implicit in the hazard analysis is the consideration of relative risks. This includes consideration of the frequency with which a pathogen occurs, the levels of the micro-organism when it does occur, and its relative pathogenicity and severity in relation to public health concerns.

These concepts can be explored more fully by considering two examples. The first is *Staphylococcus aureus*. While a well-documented foodborne pathogen, low levels of this micro-organism are commonly found and tolerated in a variety of raw and ready-to-eat products. This reflects the fact that the bacterium is ubiquitously associated with humans and livestock and that until its population density exceeds *c.* 10^5 g^{-1}, the risk of this toxigenic micro-organism producing an adverse effect in humans is negligible. By concluding that low levels of this micro-organism do not represent a significant hazard, the individual performing the hazard analysis has *de facto* established a microbiological criterion. For example, the US National Advisory Committee on Microbiological Criteria for Foods (NACMCF) concluded that for cooked ready-to-eat shrimp <500 *S. aureus* g^{-1} do not represent a risk, and recommended its use as an indicator of process integrity. Unlike the formal documents produced by organizations such as the NACMCF or the International Commission for Microbiological Specifications for Foods (ICMSF), in most instances the individuals performing hazard analyses often do not state or articulate only poorly their microbiological criteria and the assumptions underlying them.

The second example is *Escherichia coli* O157:H7. Recently, the USDA Food Safety and Inspection Service went through a similar risk evaluation process in establishing a microbiological criterion for *E. coli* O157:H7 in ground beef. The severity of the disease (haemorrhagic colitis, haemolytic uremic syndrome) and its epidemiological link to the product in question had been well established. Analysis of outbreak data indicated that the consumption of low levels (*c.* 1–10 cfu g^{-1} in ground beef; lower levels in dry cured salami) can produce outbreaks. Finally, surveys indicate that a substantial portion (i.e. *c.* 25%) of US consumers prepare hamburgers to a degree of 'doneness' that will not assure elimination of all *E. coli*. Using this risk evaluation-based approach, it was evident that the level of *E. coli* O157:H7 present in ground beef that would not represent a significant risk of disease was well below both the normal serving and sampling sizes. While a misnomer, the end result of this semi-quantitative hazard analysis was the establishment of an effectively 'zero-tolerance', based on negative results in a specified quantity of product (25 g) that is analysed by a specified method or its analytical equivalent.

It is evident in these two examples that to perform an adequate hazard analysis, one must be able to take into account quantitative aspects of the relative risks associated with various pathogenic micro-organisms. This requires that the individual performing the hazard analysis has an understanding of microbiological criteria that relate the fre-

quency or levels of specific pathogens to the food safety risks that will be tolerated by a society. This, in turn, will serve as the basis for the design of food processing systems to achieve the needed degrees of assurances as reflected in their critical limits. It is also evident that the ability to perform a meaningful hazard analysis would be greatly enhanced by the development of improved techniques in quantitative microbial risk assessment.

Establishing critical limits

The second area of HACCP where microbiological criteria play an integral role is the establishment of critical limits. Experience has indicated that this is the most difficult part of developing a HACCP plan because it requires that the developer makes concrete decisions concerning the performance of the system, balancing the cost associated with unnecessary stringency with the risk of inadequate control of a microbiological concern. However, the entire purpose of a critical limit is to set a pass/fail criterion that provides the basis for decisions about the operation of a critical step in a process. A CCP without a critical limit is worthless.

What is less well understood by many individuals developing or overseeing HACCP plans is that for every CCP that addresses a microbiological hazard, there is an explicit or implicit microbiological criterion. This can either be an absolute criterion (i.e. a specific upper level or frequency of a micro-organism, group of micro-organisms or product of microbial metabolism) or a performance criterion (i.e. a specified change that a process is expected to exert on the level or frequency of a micro-organism, group of micro-organisms or microbial metabolite). Both types of criteria can be used with a single CCP, a combination of multiple steps or even a complete integration of all unit operations making up the food production process (i.e. end-product criteria).

Part of this lack of appreciation of the importance of microbiological criteria to HACCP arises from the fact that while the goal is control of pathogenic micro-organisms, most critical limits are based on control of a physical or chemical attribute. For example, the canning of low-acid canned foods requires that the product be heated for a specified time at a specified temperature. However, underlying this physical attribute-based critical limit (i.e. time and temperature) is a microbiological performance criterion; a reduction in the levels of *Clostridium botulinum* spores by a factor of 10^{12}. This performance criterion, in turn, reflects risk management decisions concerning the known severity of the hazard and 'tolerated' risk associated with the potential for botulism outbreaks.

It needs to be emphasized when dealing with the conceptual basis for HACCP, that the degree of stringency associated with controlling risks, like the risks themselves, is a relative attribute. Stringency can be varied depending on both the desires and concerns of society and the effectiveness of current technologies. The level of risk tolerated by a society is complex, but is often translated into the costs, including both economic and aesthetic. For example, one could assure control of *Salmonella* spp. in poultry products by only selling canned products. While this is a technologically and economically feasible approach, the aesthetic cost is not acceptable for the majority of the US population. Alternatively, one could raise and slaughter the animals near sterile conditions and test each animal for pathogens before shipping. However, the cost burden that would be passed onto the consumer would likely make the product non-viable economically. Integrated into these costs are also ethical considerations and issues related to human suffering.

It is obvious that one can control the relative stringency of a food production process by manipulating one or more of the critical limits associated with the process' CCPs. The immediate implication is that to be fully effective, a HACCP plan developer must understand how the critical limit is related to the microbiological criterion underlying it, how this criterion is related to the hazard that was identified in the hazard analysis and society's expectations and regulations. Again, the development of effective microbial risk assessment techniques is critical for the

establishment of the relationship between microbiological criteria and public health impacts.

Implications for regulatory agencies

As the food industry moves toward the widespread use of HACCP, the need for a clear understanding of the relationship among HACCP, microbiological criteria and risk assessment is evident. Too often they have been considered separately, in part because we have not had the conceptual and scientific tools to integrate the approaches. However, we have reached the stage where complex issues must be addressed with a substantially higher degree of sophistication. As HACCP is required increasingly for food production, some of the areas in which regulatory agencies will likely be called upon to become more involved are listed below.

1. Assess the current technological status of the industry for its ability to control pathogenic micro-organisms. This includes identifying areas where additional technologies are needed and stimulating appropriate innovation.
2. Foster the acquisition and dissemination of epidemiological, public health, and microbiological data on: (a) incidence of foodborne disease; (b) factors that contribute to the incidence of outbreaks and sporadic cases; and (c) microbiological profiles and characterizations of major food products and processes. These data will be essential if industry and government are going to be able to conduct meaningful hazard analysis.
3. Articulate realistic societal food safety goals through the establishment of both public health-based targets, and the elucidation of microbiological criteria that will help the food industry conduct hazard analyses and establish critical limits that reflect these targets.
4. Develop improved techniques in microbiological risk assessment that provide a more objective means for measuring and ranking microbial food safety hazards.
5. Develop improved means for evaluating the relative performance of HACCP systems and approaches in order to develop more objective means for assessing 'equivalence' for products in international trade.
6. Provide clear examples of the levels of sophistication and stringency that food industries are expected to achieve in the development of mandatory or voluntary HACCP programmes.
7. Review existing criteria in relation to their scientific basis and their ability to provide the level of the microbiological food safety required by society.